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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/583,310	05/30/2000	John R. Cashman	16663-000120US	5075

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EXAMINER

STEADMAN, DAVID J

ART UNIT

PAPER NUMBER /0

1652

DATE MAILED: 02/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/583,310

Applicant(s)

CASHMAN ET AL.

Examiner

David J. Steadman

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-5 and 37-39 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 3 and 5 is/are rejected.
- 7) ☒ Claim(s) 4 and 37-39 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Application Status

Claims 3-5 and 37-39 are pending in the application.

Election/Restrictions

1. Applicants' election with traverse of Group I, claims 3-5 and 37 is acknowledged. Applicants traverse the restriction requirement on the grounds that the Groups have identical classifications and the sequences of SEQ ID NOs:5-8 have been searched in a prior application (08/617,671, now abandoned) and a co-examination of the claims of Groups I and II would therefore not result in a serious burden on the examiner. In view of applicants' arguments regarding a prior search of the sequences of SEQ ID NOs:5-8 in a prior application, the examiner has withdrawn the restriction requirement set forth in Paper No. 7 and will therefore examine claims 3-5 and 37-39 on the merits.

Specification/Informalities

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 121 as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

If applicant desires priority under 35 U.S.C. 121 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Claim Objections

3. Claim 3 is objected to because of the use of the term "strong stringency" as this is non-standard terminology. It is suggested that applicants replace the term with, for example, "high stringency".
4. Claim 3 is objected to because of the recitation of "flavin-containing monooxygenase FMOS". It is suggested that applicants replace the term with, for example, "flavin-containing monooxygenase (FMOS)".
5. Claim 3 is objected to as being grammatically incorrect in the recitation of "strong stringency conditions with" and "washed". It is suggested that applicants replace the term with, for example, "high stringency conditions of" and "washing", respectively.
6. Claims 3-5 are objected to because of the recitation of "Claim". It is suggested that "Claim" be replaced with "claim".

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 3-5 and 37-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
8. Claim 3 (claims 4, 5, and 37-39 dependent therefrom) is unclear in the recitation of "from SEQ ID NO:5". It is suggested that applicants replace the term with, for example, "of SEQ ID NO:5".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Dolphin (IDS reference AA; EMBL Accession Number Z47552, 12 January, 1995). Claim 3 is drawn to a DNA sequence encoding an adult human liver flavin-containing monooxygenase (FMOS) that hybridizes to an oligonucleotide probe of at least 25 contiguous nucleotides of SEQ ID NO:5. Dolphin teaches a polynucleotide that is 99.5 % identical to the polynucleotide of SEQ ID NO:5 of the instant application with mismatches at nucleotides 129, 472, 717, and 1458 of SEQ ID NO:5 (see sequence comparison). Dolphin teaches that the polynucleotide was isolated from the adult human liver and encodes a flavin-containing monooxygenase type 3 (FMO3) enzyme. This anticipates claim 3 as written. It is noted that the date listed on the sequence comparison is 17 April, 1996. However, in a direct communication with the European Molecular Biology Laboratory (EMBL), the examiner was informed that the date of public availability of the sequence of Dolphin was 12 January, 1995.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dolphin in view of Sambrook (*Molecular Cloning*, 2nd Edition, 1989, Cold Spring Harbor Laboratory Press, 17.10-17.27). Claim 5 is drawn to a prokaryotic or eukaryotic host cell comprising a DNA as encompassed by claim 3 inserted into an expression vector with a heterologous regulatory control sequence.

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Dolphin teaches the DNA sequence as described above. Dolphin does not teach an expression vector with a heterologous regulatory control sequence comprising the DNA of Dolphin in a prokaryotic or eukaryotic host cell.

Sambrook teaches expression vectors for prokaryotic or eukaryotic polypeptide expression and methods of inserting a DNA into said vectors.

Therefore, it would have been obvious to one of ordinary skill in the art for an expression vector with a heterologous regulatory control sequence comprising the DNA of Dolphin in a prokaryotic or eukaryotic host cell. One would have been motivated for an expression vector with a heterologous regulator control sequence comprising the DNA of Dolphin in a prokaryotic or eukaryotic host cell in order to express the encoded polypeptide for enzymatic characterization or antibody production. One would have a reasonable expectation of success for an expression vector with a heterologous regulatory control sequence comprising the DNA of Dolphin in a prokaryotic or eukaryotic host cell because of the results of Dolphin and Sambrook. Therefore, claim5, drawn to a prokaryotic or eukaryotic host cell comprising a DNA as encompassed by claim 3 inserted into an expression vector with a heterologous regulatory control sequence would have been obvious to one of ordinary skill in the art.

Conclusion

11. Claims 4 and 37-39 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.
12. No claim is in condition for allowance.

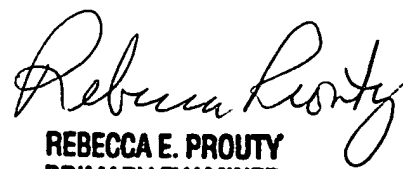
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:30 am to 2:00 pm and from 3:30 pm to 5:30 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for this Group is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

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David J. Steadman, Ph.D.


REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1800
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